1 of 3

PATENT
Docket No. 246472001600

CERTIFICATE OF HAND DELIVERY

I hereby certify that this correspondence is being hand filed with the United States Patent and Trademark Office in Washington, D.C. on May 12, 2003.

Kathleen J. Farrar

Kathleen J. Farrar

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In the application of:

Alfred SCHMIDT et al.

Serial No.: 09/646,355

Filing Date: September 18, 2000

For: MEDICAMENT FOR PREVENTING AND/OR TREATING A MAMMARY CARCINOMA, CONTAINING A STEROIDAL AROMATASE INHIBITOR

Examiner: San-ming R. Hui

Group Art Unit: 1617

APPELLANTS' REPLY BRIEF

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

Kindly consider this reply to the Examiner's Answer dated March 12, 2003. Appellants thank the Examiner for withdrawing the rejection of claims 17-24 under 35 USC 112, second paragraph. The appeal from the final rejection of claims 17-24 under 35 USC 103(a) on Brodie and Messenger taken in view of Hanson remains for decision. Appellants respond in this Reply Brief only to new arguments and to issues where the Examiner's Answer misapprehended appellants' Opening Brief.

ARGUMENT

A. The Examiner Erred In Stating That "The Claims Fail To Recite Any Specific Steps For Making Or Preparing The Envisioned Composition."

The Examiner's position in the Answer relies in part on the proposition, stated in various different ways, that the claims do not recite "any specific steps" for making the claimed composition. See, e.g., page 3, line 18 – page 4, line 3; page 6, lines 11-16. Simple examination of the claim language reveals the Examiner's error. Claim 17 on appeal, with paragraphing added for emphasis, states:

> 17. A method of making a medicament for the prophylaxis or treatment of mastocarcinoma, comprising
>
> combining
>
> a therapeutically or prophylactically effective amount of an active ingredient comprising a steroidal aromatase inhibitor and containing no antigestagens and
>
> a substance for promoting skin penetration
>
> so as to avoid systemic action of the active ingredient.

Claim 17, and thus claims 18-24 depending from it, sets forth a one-step method, of "combining" two ingredients. This method is carried out *in such a way* as to produce the result of avoiding the systemic action of the active ingredient. Statements of intended result in method claims are entitled to patentable weight *if* such statements limit the way in which the method is carried out. In this case, appellants rely specifically on the claim limitation, "so as to avoid systemic action of the active ingredient," to delineate this invention from other processes in which the combining step is carried out so as to produce a medicament for the prevention or treatment of mastocarcinoma that acts systemically. In those other processes that do not fall within the scope of this invention, the quantities of ingredients combined in the combining step do not produce the claimed result of "avoid[ing] systemic action of the active ingredient."

Accordingly, the Examiner's argument that the claims on appeal do not forth method steps is not supported by the claim language itself.

B. The Examiner Continues To Improperly Fail To Give Weight To the Preambles Of the Claims In Making The Obviousness Rejection.

Appellants have already anticipated in their Opening Brief a good portion of the Examiner's argument on page 5 of the Answer that the preambles of the appealed claims are not limitations. The case law relied on by the Examiner predates and is cited in the *Pitney Bowes* case quoted and discussed by appellants at pages 8 and 9 of their Opening Brief. In responding to appellants the Examiner did not take issue with the points that appellants made and failed to deal with the law as enunciated specifically in *Pitney Bowes*. In particular, the Examiner failed to take issue with a crucial aspect of appellants' argument, as stated on page 8 of the Opening Brief, that the claimed method is not an open-ended method of combining two ingredients but is instead a method for making a medicament that, because of its particular claimed intended use, has certain characteristics which the method of making the medicament must be carried out to produce when the end product is used. Appellants have consistently argued this interpretation of the preamble of the appealed claims, on which they are entitled to rely to demonstrate the patentability of the claimed subject matter over the prior art.

The Federal Circuit confirmed the validity of this argument in just the past few days. Citing *Catalina Mktg. Int'l Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808-09, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002), the court stated that "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." *Invitrogen Corp. v. Biocraft Mfg., L.P.*, 2003 U.S. App. LEXIS 8651 at *15 (Fed. Cir. App. No. 02-1207, decided May 7, 2003) (copy of slip opinion attached). In line with *Invitrogen*, appellants' arguments demonstrate that the broadest *reasonable* construction of appellants' claims requires treatment of the preambles as limitations because appellants have disclaimed any coverage of their claims beyond methods which satisfy the preambles. Since the

Examiner's position relies heavily on refusing to give patentable weight to the claim preambles, the rejection of appellants' claims over the prior art, which does not suggest anything akin to the ability of the claimed invention to produce a composition for treatment or prophylaxis of mastocarcinoma while avoiding systemic action of the active ingredient, contrary to the prior art.

Pages 5-7 of the Answer dismiss appellants' arguments regarding the failure of the prior art to suggest the claimed method of combining the claimed ingredients by stating that the preambles are not limiting and that the statement that the method is carried out so as to avoid systemic action of the active ingredient is likewise not a limitation. Since the Examiner's legal position cannot be sustained, likewise the rejection of claims 17-24 cannot be sustained on the stated basis.

C. The Examiner's Reliance On *In re Dillon* Is Misplaced – The Examiner Has Incorrectly Treated Appellants' Claims As Composition Claims.

The Examiner cites *In re Dillon*, [919 F.2d 688,] 16 USPQ2d 1897, 1900 (Fed. Cir. 1990) (en banc), for the proposition "that the recitation of [a] new utility for an old and well-known composition does not render that composition new." Answer, page 4. The Examiner then proceeds to rely on *Dillon* to support the proposition that "[t]he mere mentioning of intended treatment use or prophylaxis use as herein recited fails to provide a distinguishing claim limitation, unless that amount is <u>different</u> from the prior art and <u>critical</u> to the use of the claimed composition." *Id.*; emphasis in original. The problem with these statements is that they are not applicable to this case.

The error in the Examiner's logic is the conflation of appellants' claims with composition claims, which they are not. *Dillon* involved the patentability of *composition*, not method of making, claims.[1] The court in *Dillon* held, in essence, that an otherwise unpatentable composition is not patentable simply because the inventor's motivation in making the claimed

---

[1] The court affirmed the Board's decision holding Dillon's method of use claims to be unpatentable, but *only* because Dillon did not argue the patentability of her method claims separately from her composition claims. *Id.* at 695, 16 USPQ2d at 1903.

composition is different from the motivation shown in the prior art. *Id.* at 693, 16 USPQ2d at 1902. The court was careful not to make any statement that might have been relevant to Dillon's method claims:

> We make no judgment as to the patentability of claims that Dillon might have made and properly argued to a method directed to the novel aspects of her invention, except to question the lack of logic in a claim to a method of reducing particulate emissions by combusting. Suffice it to say that we do not regard Durden as authority to reject as obvious every method claim reading on an old type of process, such as mixing, reacting, reducing, etc. The materials used in a claimed process as well as the result obtained therefrom, must be considered along with the specific nature of the process, and the fact that new or old, obvious or nonobvious, materials are used or result from the process are only factors to be considered, rather than conclusive indicators of the obviousness or nonobviousness of a claimed process. When any applicant properly presents and argues suitable method claims, they should be examined in light of all these relevant factors, free from any presumed controlling effect of Durden. Durden did not hold that all methods involving old process steps are obvious; the court in that case concluded that the particularly claimed process was obvious; it refused to adopt an unvarying rule that the fact that nonobvious starting materials and nonobvious products are involved ipso facto makes the process nonobvious. Such an invariant rule always leading to the opposite conclusion is also not the law. Thus, we reject the Commissioner's argument that we affirm the rejection of the method claims under the precedent of Durden.

Id. at 695, 16 USPQ2d at 1903. Appellants are not claiming a composition in the appealed claims, so *Dillon* is not apposite to this case.

Page 6 of the Answer boils down to the proposition that the claimed method is "a simple mixing of the old and well known components together and, thuis, reading on the product comprising the same components." [Emphasis in original.] Appellants' claims do not "read on" a product, and appellants' claims do not "read on" simply mixing the claimed ingredients, as appellants have argued repeatedly. The Examiner's error in claim interpretation is fatal to the rejection.

D. The Examiner Has Clearly Misapplied The Prior Art To The Claims As Properly Construed.

The Answer places great stock in the failure of the broadest claims to recite a specific penetration enhancer or to claim critical amounts of penetration enhancer. See, e.g., paragraph bridging pages 5-6. The Examiner also relies heavily on the proposition that "the claims essentially encompass all penetration enhancers known in the pharmaceutical art." Answer, page 6. As explained above and in the Opening Brief, however, the Examiner's position is incorrect – the claims cover only methods in which the ingredients are combined so as to avoid systemic action of the active ingredient, which excludes penetration enhancers which do not avoid systemic action or combining amounts of otherwise suitable penetration enhancers in such a way that would not avoid systemic action of the active ingredient.

The Examiner did not contradict appellants' argument that Brodie does not teach the use of topical formulations and directs persons of ordinary skill in the art away from the invention of this application by teaching the sustained release administration of steroidal aromatase inhibitors systemically so as to achieve serum levels sufficient to produce the therapeutic effects disclosed in Brodie. Likewise, the Examiner did not contradict appellants' argument that Messenger does not teach or suggest to persons of ordinary skill in the art that *mastocarcinoma* may be treated in accordance with the claimed method, but is instead directed to the treatment and prevention of *hair loss*. Finally, the Examiner did not contest appellants' point that Hanson does not disclose any use of DMSO in cancer treatment of any kind and says nothing about the avoidance of systemic action. Thus, without hindsight resort to appellants' disclosure, persons of ordinary skill in the art to which the invention as claimed pertains would have had no reason to consider Brodie, Messenger or Hanson as disclosures that suggest the claimed invention.

The Answer instead makes a startling argument at pages 5-6, that appellants' claims are unpatentable because "one of ordinary skill in the art possessing the examiner cited [sic] prior art teachings would therefore be motivating [sic] to incorporate the old and well known prior art penetration enhancer herein claimed, DMSO, into the topical composition of Messenger[,]

thereby enhancing the systemic absorption of the active agent." [Emphasis supplied.] That is exactly what appellants' claims do *not* cover – appellants' claims require avoidance of the very result the Examiner claims Messenger discloses. The Examiner's logic stands the claims on their heads.

CONCLUSION

For the foregoing reasons and the reasons set forth in appellants' Opening Brief, the Board should reverse the final rejection of claims 17-24 in this application.

In the event that the transmittal letter is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief is required, appellants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 246472001600.

Respectfully submitted,

Dated: May 12, 2003 By: _____

Barry E. Bretschneider
Registration No. 28,055

Morrison & Foerster LLP
1650 Tysons Boulevard, Suite 300
McLean, Virginia 22012-3915
Telephone: (703) 760-7743
Facsimile: (703) 760-7777

1 of 3 DOCUMENTS

INVITROGEN CORPORATION, Plaintiff-Appellant, v. BIOCREST MANUFACTURING, L.P., STRATAGENE HOLDING CORPORTION and STRATAGENE, INC., Defendants-Cross Appellants.

02-1207, 02-1260

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2003 U.S. App. LEXIS 8651

May 7, 2003, Decided

PRIOR HISTORY:
*1 Appealed from: United States District Court for the Western District of Texas. Judge Sam Sparks.

CORE TERMS: cell, competence, coli, improved, patent, temperature, preamble, invention, freezing, protein, seeds, summary judgment, preparation, gene, construing, transformable, examiner, molecule, artisans, minute, comprising, numerical, correctly, specification, open-ended, embodiment, scientific, replicate, disclaim, recited

COUNSEL:
Francis M. Wilkstrom, Parsons Behle & Latimer, of Salt Lake City, Utah, argued for plaintiff-appellant. With him on the brief were C. Kevin Speirs and Kristine Edde Johnson. Of counsel on the brief was Alan W. Hammond, Invitrogen Corporation, of Carlsbad, California.

Marc R. Labgold, Ph.D., Patton Boggs LLP, of McLean, Virginia, argued for defendants-cross appellants. With him on the brief were Kevin M. Bell and Laura A. Donnelly. Of counsel on the brief was Richard J. Oparil, Patton Boggs LLP, of Washington, DC.

JUDGES:
Before RADER, BRYSON, and DYK, Circuit Judges.

OPINIONBY:
RADER

OPINION:

RADER, Circuit Judge.

On summary judgment, the United States District Court for the Western District of Texas determined that Biocrest Manufacturing, L.P., Stratagene Holding Corporation, and Stratagene, Inc. (collectively Stratagene) did not infringe Invitrogen Corporation's (Invitrogen's) U.S. Patent No. *4,981,797* (issued Jan. 1, 1991) (the *'797* patent). Invitrogen Corp. v. Biocrest Mfg., L.P., No. A 01 CA 167 SS (W.D. Tex. Nov. 2, 2001). Because the district court incorrectly construed the *2 claims of the *'797* patent, this court vacates and remands.

I.

The '797 patent involves DNA technology. DNA molecules have nucleotide sequences called genes that act as blueprints for proteins. Modern medicine may supplement the production of important proteins in the body to treat various maladies. These treatment regimes require large quantities of a particular gene or its corresponding protein. To produce proteins, a laboratory may introduce a DNA molecule containing a particular gene into the bacterium E. coli, which serves as a factory to replicate many copies of the DNA molecule and its gene. When an E. coli cell replicates by cell division, the DNA in that E. coli cell also replicates, providing an increased number of gene sequences from which protein can be expressed. Thus, the E. coli can serve as a factory to produce important proteins.

The '797 patent claims a process for making E. coli cells with an enhanced capacity to accept foreign DNA. A cell that accepts foreign DNA is called a transformable cell. The transformable cell's capacity to accept foreign DNA is called its competence. The '797 patent thus claims a method of producing transformable E. coli cells with improved *3 competence. The foreign DNA is generally plasmid DNA -- a relatively small DNA molecule having a looped circular shape. Claim 1 of the '797 patent states:

1. A process for producing transformable E. coli cells of improved competence by a process comprising the following steps in order:

(a) growing E. coli cells in a growth-conducive medium at a temperature of 18 sdegreessC. to 32 sdegreessC.;

(b) rendering said E. coli cells competent; and

(c) freezing the cells.

'797 patent, col. 10, ll. 26-32 (emphases added).

Invitrogen accused Stratagene of infringing claims 1-5, 7-11, and 13-16 of the '797 patent. Stratagene makes and sells competent E. coli cell lines. Stratagene makes its cell lines by a process that includes the steps of incubating cells at 37 sdegreessC, growing the cells in a fermenter at 26 sdegreessC, and freezing the cells.

On March 12, 2001, Invitrogen filed a complaint against Stratagene in the District Court for the Western District of Texas. On August 16, 2001, the district court held a Markman hearing to construe the claims. On August 30, 2001, the district court issued an order construing the preamble term "improved competence" *4 and the growing step (a). On September 11, 2001, Stratagene filed a motion for summary judgment of noninfringement based on the district court's claim construction. On November 2, 2001, the district court granted Stratagene's summary judgment motion. On January 31, 2002, the district court issued a final judgment dismissing the action.

Invitrogen appealed the district court's summary judgment of noninfringement. Invitrogen asserts that the district court erred in concluding that the growing step (a) excludes all cell growth carried out above 32 sdegreessC. Invitrogen

also disputes that the preamble term "improved competence" limits the claims. Stratagene cross-appealed. Stratagene asserts that the district court erred in concluding that the preamble term "improved competence" means that competence is "generally increased" with no numerical limitation.

This court has jurisdiction under *28 U.S.C. § 1295*(a)(1) (2000).

II.

This court reviews without deference a district court's grant of summary judgment, and draws all reasonable factual inferences in favor of the non-movant. *Cortland Line Co. v. Orvis Co., 203 F.3d 1351, 1355-56, 53 USPQ2d 1734, 1736 (Fed. Cir. 2000).* *5 This court decides for itself whether "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c).

A court determines patent infringement by first construing the claims and then applying the construed claims to the accused process or product. *Markman v. Westview Instruments, Inc., 52 F.3d 967, 976, 34 USPQ2d 1321, 1326 (Fed. Cir. 1995)* (en banc), aff'd, *517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 (1996).* This court reviews a district court's claim construction without deference. *Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454, 46 USPQ2d 1169, 1174 (Fed. Cir. 1998)* (en banc).

Claim language generally carries the ordinary meaning of the words in their normal usage in the field of invention. *Toro Co. v. White Consol. Indus., 199 F.3d 1295, 1299, 53 USPQ2d 1065, 1067 (Fed. Cir. 1999).* While this "ordinary meaning" rule is usually expressed as a pat formula, the context supplied by the field *6 of invention, the prior art, and the understanding of skilled artisans generally is key to discerning the normal usage of words in any claim. See, e.g., *Hoechst Celanese Corp. v. BP Chems., Ltd., 78 F.3d 1575, 1579 (Fed. Cir. 1996).*

The applicant may also act as his own lexicographer and use the specification to implicitly or explicitly supply new meanings for terms. *Bell Atl. Network Servs., Inc. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268, 59 USPQ2d 1865, 1870-71 (Fed. Cir. 2001).* While prosecution history estoppel does not apply to determining literal claim scope, statements to an examiner during prosecution before the United States Patent and Trademark Office (PTO) may also illuminate the scope of the claims. See *Ballard Med. Prods. v. Allegiance Healthcare Corp., 268 F.3d 1352, 1358, 60 USPQ2d 1493, 1498 (Fed. Cir. 2001).* Moreover, an applicant may actually disclaim claim scope during prosecution. *Id. at 1361.* The applicant, however, must clearly and unambiguously express any such surrender of subject matter during prosecution. See *Middleton, Inc. v. Minn. Mining & Mfg. Co., 311 F.3d 1384, 1388, 65 USPQ2d 1138, 1141 (Fed. Cir. 2002);* *7 *Inverness Med. Switz. GmbH v. Princeton Biomeditech Corp., 309 F.3d 1365, 1372, 64 USPQ2d 1926, 1932 (Fed. Cir. 2002).*

A. The "Growing" Step

The district court construed the growing step (a) to mean that "growth must be performed at a temperature within 18 sdegreessC to 32 sdegreessC, inclusive,

and that at no time prior to freezing can the temperature of the cells exceed 32 sdegreessC." Invitrogen Corp. v. Biocrest Mfg., L.P., No. A 01 CA 167 SS, slip op. at 10 (W.D. Tex. Aug. 30, 2001) (Claim Construction Order). The district court rejected Invitrogen's argument that the term "comprising" in the preamble meant that claim 1 was open-ended and thus allowed an additional step of growing cells at 37 sdegreessC before the growing step (a). The district court instead read the prosecution history of the *'797* patent to disclaim all growth outside the range in step (a). In other words, the district court's claim interpretation foreclosed any growth other than growth in the claimed temperature range.

When entering a rejection during prosecution of the application that led to the *'797* patent, the PTO examiner stated that 18 sdegreessC to 32 sdegreessC was essential *8 to the invention. The applicants then amended the claims to replace "less than 37 sdegreessC" with "18 sdegreessC to 32 sdegreessC" in claim 1. The applicants then stated that their amendment ensures that the claimed invention is different from prior art showing growth at 37 sdegreessC. Furthermore, the applicants noted that the invention avoids undesirable effects of growth at 37 sdegreessC. On the basis of this rather sketchy record, the district court concluded that the applicants had disclaimed all growth outside the range of 18 sdegreessC to 32 sdegreessC. Therefore the district court interpreted the claim to exclude any growth outside that range.

To the contrary, claim 1 does not address and therefore permits growth before the steps disclosed in the claim at temperatures outside the range of 18 sdegreessC to 32 sdegreessC. At the outset, the claim language itself does not preclude growth in advance of the first step in the claim. Step (a) of claim 1 specifies E. coli population growth at 18 sdegreessC to 32 sdegreessC. Step (b) specifies rendering competent the cells that immediately result from step (a). Step (b) conveys this by stating "rendering said E. coli cells competent" *9 (emphasis added). The cells that are rendered competent in step (b) include specific cells formed at 18 sdegreessC to 32 sdegreessC in step (a). At no point has this claim addressed or limited any activities that may have occurred before steps (a) and (b).

The transition "comprising" in a method claim indicates that the claim is open-ended and allows for additional steps. See *Vivid Techs., Inc., v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 811, 53 USPQ2d 1289, 1301 (Fed. Cir. 1999)* (citing *Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1271, 229 USPQ 805, 812 (Fed. Cir. 1986))*. Claim 1 uses the open-ended transition "comprising" to introduce the recited steps. Thus the claim signals to patent practitioners that claim 1 allows activity, even activity that produces E. coli cell growth, before the recited steps. Such activity outside the claim, of course, is not limited by the temperature range recited in claim 1. Thus, the district court erred by extending the claim's temperature restrictions beyond the reach of the claims. The claim language and its form do not restrict activities to prepare the cells that occur before the claimed method.

As noted *10 earlier, the context of this scientific field illuminates the claim's meaning and reach. The *'797* patent discusses the field of invention. In this discussion, the patent discloses that skilled artisans in this field grow and store E. coli cells at temperatures outside the range 18 sdegreessC to 32 sdegreessC in preparation for the claimed method. For example, the *'797* patent discusses preparation of master seeds by a process involving growing E. coli cells at 37 sdegreessC (col. 5, ll. 49-50). Master seeds are frozen E. coli

strains stored long-term at -70 sdegreessC. These master seeds must undergo preparation before becoming the primary seeds for use in the claimed method. The *'797* patent discloses the growth or preparation of primary seeds at 18 sdegreessC to 32 sdegreessC, but notes that artisans may use higher temperatures because the resulting primary seeds "can be used to prepare competent cells from a culture grown at a lower temperature" (col. 6, ll. 5-13). The specification thus supplies context about the understanding of skilled artisans and the field of invention that confirms that claim 1 does not preclude growth before the first step in the inventive process.

The prosecution *11 history does not show any clear and unambiguous disavowal of steps in advance of the step of growing E. coli cells in the claimed temperature range. By amending the claims to replace "less than 37 sdegreessC" with "18 sdegreessC to 32 sdegreessC" the applicants did not exclude all cells with ancestral growth above 32 sdegreessC. Instead, the applicants simply specified the requirement of growth of primary cells within the required range to render the cells competent in the following step (b). In context, the applicants' statements about the undesirable effects of growth at 37 sdegreessC refer to growth at 37 sdegreessC that immediately precedes rendering the E. coli competent. The applicants did not address growth at 37 sdegreessC that occurs before initiation of the claimed method. As the inventors stated in a declaration submitted to the PTO during prosecution, the invention provided improved competence "by growing the cells at 18 sdegreessC to 32 sdegreessC before rendering the cells competent" compared to an otherwise identical process with growth at 37 sdegreessC. The applicants did not disclaim all growth above 32 sdegreessC but instead emphasized the advantages of growth at *12 18 sdegreessC to 32 sdegreessC immediately before rendering the E. coli competent.

The district court's construction would also effectively exclude the embodiment of Example 3 of the *'797* patent. This court has held that construing a claim to exclude a preferred embodiment "is rarely, if ever, correct and would require highly persuasive evidentiary support." *Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1583, 39 USPQ2d 1573, 1578 (Fed. Cir. 1996)*. This court finds no highly persuasive evidentiary support for excluding Example 3. Example 3 shows initial growth at 37 sdegreessC followed by growth at 23 sdegreessC before rendering the resulting cells competent. Specifically, Example 3 shows cells grown in a flask at 37 sdegreessC. Next Example 3 cooled the flask to about 23 sdegreessC. Finally, samples were removed at 30-minute intervals between 0 and 120 minutes before being rendered competent and transformed.

Example 3 also is not a comparative example meant to show the deleterious effect of growth at 37 sdegreessC. Table 3 shows the results of Example 3. The *'797* patent describes the results as follows: "The results of this experiment indicate that shifting *13 strain RR1 from 37sdegreess C. to 23sdegreess C. for two hours results in a 60 fold increase in the efficiency of transformation compared to a sample which does not undergo a temperature shift" (col. 10, ll. 20-24). The comparative example is the sample that "does not undergo a temperature shift," i.e., the sample removed at 0 minutes without spending any time at 23 sdegreessC. Thus, the entire context of the patent and its field of invention show that Example 3 demonstrates that even a small amount of growth in the claimed range (e.g., for 30 minutes) increases competence. Indeed the district court's construction would also exclude other embodiments disclosed in the *'797* because ancestral cells are often grown at 37 sdegreessC at some stage.

Thus, an examination of the claim language in its proper scientific context, as well as a proper reading of the prosecution history, shows that step (a) encompasses only growth immediately preceding step (b). As the claim specifies, this growth must fall in the range of 18 sdegreessC to 32 sdegreessC. Growing the E. coli at 18 sdegreessC to 32 sdegreessC in step (a) yields a mass of cells that step (b) renders competent. The claim scope thus *14 does not preclude preparatory steps in advance of step (a), including growth of E. coli at a temperature outside the step (a) range.

B. "Improved Competence"

In its claim construction order, the district court construed the term "improved competence":

The phrase "improved competence" means that the number or quantity of E. coli cells that take up and establish exogenous DNA is generally increased as compared with the number or quantity generally obtained when cells are prepared by either (1) growing the cells at 37 sdegreessC, rendering them competent, and freezing them, or (2) growing the cells at 37 sdegreessC, rendering them competent, and not freezing them.

Claim Construction Order at 10. Invitrogen asserts that the preamble term "improved competence" should not limit the claims because the term simply states an intended advantage. Stratagene counters that while the district court correctly concluded that "improved competence" limits the claims, the district court should have also construed "improved competence" to require at least a ten-fold competence increase and to require that repeated freezing and thawing does not decrease competence.

In the *15 first place, the district court correctly discerned that the preamble in this patent acts as a limitation. The district court reasoned: "In response to the Examiner's rejection, the applicants for the '797 patent amended the claims to include the 'improved competence' language" and "cannot now disavow the claim limitation of 'improved competence' because it was clearly essential for procuring the patent." Id. at 4. This court has stated that "clear reliance on the preamble during prosecution to distinguish the claimed invention from the prior art transforms the preamble into a claim limitation because such reliance indicates use of the preamble to define, in part, the claimed invention." *Catalina Mktg. Int'l Inc. v. Coolsavings.com, Inc., 289 F.3d 801, 808-809, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002)* (citing *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1375, 58 USPQ2d 1508, 1513 (Fed. Cir. 2001))*.

In an official action dated March 22, 1988, the PTO examiner rejected all claims over D. Hanahan, DNA Cloning (1985) (Hanahan), because "the claims do not require increased competency." In response, the applicants replaced "competent *16 E. coli cells" in the preamble with "E. coli cells of improved competence." The applicants stated "new claim 29 corresponds to canceled claim 1 but has been rewritten to make clear that the process gives E. coli cells of improved competence." The applicants distinguished Hanahan by arguing that the reference "does not teach the preparation of E. coli cells of improved competence" and "the cells produced according to the claimed methods have improved competence." By the amendment and the accompanying statements, the

applicants clearly relied on the preamble term "improved competence" to distinguish Hanahan. "Improved competence" thus limits the claims and is not merely a statement of intended advantage. Thus, the district court properly consulted the context of the preamble language, in this case its prosecution history, to note that it operates as a limit on claim scope.

To determine the limiting effect of the language, the district court again correctly consulted the overall context of the language. The test data in the prosecution history and the patent itself show that the claimed process provided varying amounts of increased competence. Therefore, relying on this scientific data, *17 the district court adopted a general definition of the term "improved." The district court properly declined to read into the claim any specific numerical improvement, such as a ten-fold increase in competence. At the outset, the claim language itself includes no specific numerical limitation for the "improved competence." Moreover neither the specification nor the prosecution history supplies any specific improvement measure. Thus "improved competence" requires no specific numerical limitation. This court also finds no basis for construing "improved competence" to require that repeated freezing and thawing does not decrease competence. The district court correctly construed the term "improved competence."

CONCLUSION

Because the district court erred in construing the growing step (a) and improperly granted summary judgment that Stratagene does not infringe the '797 patent based on the erroneous claim construction, this court vacates and remands for further proceedings applying this court's claim construction.

COSTS

Each party shall bear its own costs.

VACATED and REMANDED